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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,178	07/16/2003	Douglas S. Horne	8603.63	2354

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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
12/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/621,178	HORNE ET AL.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-14,17 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-14,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *NPL NIH statement*.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 09/23/2008, amendment(s) to the specification is/are acknowledged. The drawing objections is/are *withdrawn*. The following new and/or reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 7-14, 17, and 18 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. The disclosed invention (i.e. "accurately locating a meridian transdermally and obtaining a value for an electrical attribute corresponding to such a meridian") and claimed invention (i.e. "locating a dermal area of [a] patient approximating a meridian"… and… "obtaining, from [a] probe, an electrical signal at the patient's skin corresponding to said meridian") is not supported by a well established utility and is inoperative.

4. It is well established that the dielectric properties and electrical attributes of skin, conductance and/or impedance for example, are highly inhomogeneous due to the varied physiological and anatomical structures present within the multiple layers of the epidermis, the dermis, and the subcutaneous tissue (see at least pages 6-7 of Miklavcic et al. NPL submitted 05/29/07).

5. It is well-known in the art that the electrical attributes corresponding to the varied physiological and anatomical structures of the skin may be measured and directly expressed as a number of various electrical properties via electrophysiological tests, including for example at least electromyograms (EMG), electrocardiograms (ECG or EKG), electroencephalograms EEG, and/or electro-oculograms EOG, which measure the bioelectrical properties of the muscles, heart, brain, and eyes, respectively.

6. However, considerable debate within the scientific community exists whether acupuncture points, acupressure points, and/or meridian lines may be directly measured, expressed as, and/or even associated with the above electrical attributes. The Examiner respectfully submits that the disclosed invention is not supported by a well established utility and is inoperative.

7. As evidence of the lack of scientific foundation for acupuncture points, acupressure points, and/or meridian lines, the Examiner cites the consensus statement issued by the National Institute of Health (NIH) in 1997 (NIH Consensus Statement 1997 Nov 3-5; 15(5):1-34, available at http://consensus.nih.gov/1997/1997acupuncture107html.htm, provided herewith, and hereinafter “the NIH panel”).

8. In the statement (especially section 3) the NIH panel states *inter alia:*

- *“Despite considerable efforts to understand the anatomy and physiology of the "acupuncture points," the definition and characterization of these points remain controversial. Even more elusive is the scientific basis of some of the key traditional Eastern medical concepts such as the circulation of Qi, the meridian system, and*

other related theories, which are difficult to reconcile with contemporary biomedical information but continue to play an important role in the evaluation of patients and the formulation of treatment in acupuncture."

9. The NIH panel acknowledges the potential therapeutic benefits of acupuncture; however, they argue that the scientific basis of meridians is/are subject to scrutiny under the current biomedical understanding of the electrophysiological nature of the human body. As such the Examiner asserts the disclosed and claimed invention is not supported by a well established utility and is inoperative.

10. Moreover, the Examiner notes for exemplary purposes a hypothetical situation. A number of the primary meridian lines run along a patient's chest and adjacent the underlying heart. In measuring the conductance of the skin "approximating the meridian" and "obtaining, from [a] probe, an electrical signal at the patient's skin corresponding to said meridian", a number of electrical signals will be measured including at least EMGs and ECGs. It is unclear how the present disclosed and claimed invention would be able to distinguish the measured electrophysiological signals and "accurately locat[e] a meridian transdermally and obtain a value for an electrical attribute corresponding to such a meridian" using the purported well established utility and the purported operability.

11. The Examiner respectfully requests Applicant provide substantiated evidence that the disclosed invention is both (a) supported by a well established utility and (b) is operative.

12. The Examiner reiterates and emphasizes for the record at least the following elements of the instant disclosure and claimed invention that may be considered not supported by a well established utility and inoperative:

- *Specification page 10 reads in part: "A dermal area corresponding to a meridian exhibits higher conductivity and, hence, lower resistivity, than adjacent, non-meridian containing dermal areas. A relatively high conductance value, or low resistance value, may then be used to more accurately isolate a dermal area corresponding to a meridian."*
- *Specification page 11 reads in part: "As a result, one aspect of the present invention is directed to implementing a probe having physical qualities capable of objectively detecting and analyzing electrical signals corresponding to a meridian."*
- *Specification page 11 reads in part: "An electrical signal may comprise a conductance value or a resistance value corresponding to the dermal area. Where a conductance value is obtained from a probe, a meridian may be located where the conductance value is significantly greater than an adjacent dermal area. On the other hand, where a resistance value is obtained, a resistive value significantly less, than an adjacent dermal area may indicate a location of a meridian."*
- *Specification page 12 reads in part: "When the measured conductance value is substantially greater than the previously obtained conductance value, the amount of pressure corresponding to the measured conductance value may be maintained 36 and a meridian signal obtained there from".*

- *Specification page 13 reads in part: "A feedback loop 46,49 and 50 may compare a first detected meridian signal to a second detected meridian signal and compare the relationship between the first and second detected meridian signals to compute and adjust the input that drives the biasing element 48".*

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 7-14, 17, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosed invention (i.e. "accurately locating a meridian transdermally and obtaining a value for an electrical attribute corresponding to such a meridian") and claimed invention (i.e. "locating a dermal area of [a] patient approximating a meridian"… and… "obtaining, from [a] probe, an electrical signal at the patient's skin corresponding to said meridian") is not enabled.

15. The Examiner notes that the measured electrical attributes of the skin appear to be conductance in the instant Specification and Applicant appear to correlate increases and decreases in the value of conductance with meridians (see paragraph 10 above). However it is indeterminate how these relationships are established and what scientific

basis is relied upon in establishing such relationships between a measured skin conductance and a location or signal of a meridian. Not only does the disclosed invention appear to be unsupported and inoperative, the claimed subject matter does not appear to be described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See paragraphs 4-12 above.

Response to Arguments

16. Applicant's arguments filed 09/23/2008 have been fully considered but they are not persuasive. Applicant argues the rejections of the claims under 35 U.S.C. 101 and 112.1, specifically arguing (a) the rejections fail to establish the claimed invention lacks utility and (b) it is not the place of the Office to determine that a scientific debate is settled or when it is not.

17. The Examiner disagrees, maintains the rejection as set forth and reiterated above, and in response notes the following:

18. In response to Applicant's argument (a) that the rejections fail to establish the claimed invention lacks utility, independent claims 1 and 11 positively recite "locating a dermal area of [a] patient approximating (proximate) a meridian"... and... "obtaining, from [a] probe, an electrical signal at the patient's skin corresponding to said meridian"). The claims rely not only upon the existence of meridians for completeness and patentability, but also rely upon the ability to accurately determine the location of the

meridians. Because a meridian must be necessarily present in order to "approximate a meridian" and to “obtain, from said probe, an electrical signal at the patient’s skin corresponding to said meridian”, claims 1 and 11 recite within the scope of invention the ability to determine a location of a meridian.

19. Moreover claims 17 and 18, depending from claims 1 and 11, respectively, positively recite “further comprising locating said meridian by: locating successive dermal areas approximating said meridian; said user statically contacting said successive dermal areas with said probe; allowing said probe to dynamically vary a pressure applied by said probe to said successive dermal areas in accordance with said feedback signal; and determining a dermal location corresponding to said meridian before obtaining said electrical signal corresponding to said meridian”.

20. Reiterating from above and submitting as evidence, the Examiner notes the NIH panel acknowledges the potential therapeutic benefits of acupuncture; however, they argue that the scientific basis of meridians is/are subject to scrutiny under the current biomedical understanding of the electrophysiological nature of the human body. As such the Examiner asserts the disclosed and claimed invention is not supported by a well established utility, is inoperative, and is not enabled. See paragraphs 3-15.

21. In response to Applicant’s argument (b) that it is not the place of the Office to determine that a scientific debate is settled or when it is not, the Examiner notes the Office is not attempting to determine whether a scientific debate is settled or not, but conversely is questioning the operativeness of the disclosed and claimed invention

because they do not appear to conform to the known laws of physics or chemistry and the current evidence contravenes established scientific principles. MPEP 2107.01 states *inter alia*:

- *"Second, 35 U.S.C. 101 serves to ensure that patents are granted on only those inventions that are "useful." This second purpose has a Constitutional footing — Article I, Section 8 of the Constitution authorizes Congress to provide exclusive rights to inventors to promote the "useful arts." See Carl Zeiss Stiftung v. Renishaw PLC, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991). Thus, to satisfy the requirements of 35 U.S.C. 101, an applicant must claim an invention that is statutory subject matter and must show that the claimed invention is "useful" for some purpose either explicitly or implicitly. Application of this latter element of 35 U.S.C. 101 is the focus of these guidelines.*
- *"Deficiencies under the "useful invention" requirement of 35 U.S.C. 101 will arise in one of two forms. The first is where it is not apparent why the invention is "useful." This can occur when an applicant fails to identify any specific and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966); > In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005);< In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993).* ***The second type of deficiency arises in the rare instance where an assertion of specific and substantial utility for the invention made by an applicant is not credible****."*

- *"Inventions asserted to have utility in the treatment of human or animal disorders are subject to the same legal requirements for utility as inventions in any other field of technology. In re Chilowsky, 229 F.2d 457, 461-2, 108 USPQ 321, 325 (CCPA 1956) ("There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another.* ***The character and amount of evidence needed may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized, but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases****"); In re Gazave, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967) ("Thus, in the usual case where* ***the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required.****")."*

22. The Examiner notes the rejections as set forth and reiterated above question the operativeness of the disclosed and claimed invention because they do not appear to conform to the known laws of physics or chemistry and the current evidence contravenes established scientific principles. See paragraphs 3-15.

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
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/Max Hindenburg/
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